K012637

NOV 0 7 2001

PART B: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

Alliance Medical Corporation
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Don Selvey
Vice President, Regulatory Affairs and Quality Assurance
(480) 763-5300

Date of preparation:

August 6, 2001

Name of device:

Trade/Proprietary Name: Reprocessed Phacoemulsification Tips

Common or Usual Name: Phacoemulsification Tips
Classification Name: Phacofragmentation System

Reprocessed devices:

Manufacturer	Description	Model
Alcon®	Phaco Tip Turbosonic	30KTS
Alcon®	Phaco Tip Turbosonic	30RT
Alcon®	Phaco Tip Microtip Round	30RTS
Alcon®	Phaco Tip Microtip Kelman	45KTS
Alcon®	Phaco Tip Turbosonic	45RT
Alcon®	Phaco Tip Microtip Round	45RTS
Alcon®	Phaco Tip Turbosonic	8065-7407-92
Alcon®	Phaco Tip Turbosonic	8065-7407-94
Alcon®	Phaco Tip Flared ABS	8065-740806
Alcon®	Phaco Tip Flared ABS	8065-740807
Alcon®	Phaco Tip Flared ABS	8065-740808
Alcon®	Phaco Tip Flared ABS	8065-740809
Alcon®	Phaco Tip Turbosonic ABS	8065-7900-20
Alcon®	Phaco Tip Turbosonic	8065-790021
Alcon®	Phaco Tip Turbosonic	8065-790022
Alcon®	Phaco Tip Turbosonic	8065-790023

Predicate device(s):

K980292	Alcon® Laboratories, Phacoemulsification system
K911808	Alcon® Laboratories, Alcon Series 20,000® Legacy®
K902798	Alcon® Laboratories, Automated HydroSonics®
K831836	Alcon® Laboratories, Epsilon Ultrasonic Tips & Accessories
K861380	Alcon® Laboratories, Series Ten Thousand Master
K981103	Alcon® Laboratories, Alcon Limited Reuse Ultrasonic Tip

K012637

Device description:	Phacoemulsification Tips are used to emulsify and excise cataract tissue in ophthalmic microsurgical procedures. When connected to the ultrasonic handpiece of a phacoemulsification system and activated, the Phacoemulsification Tip vibrates at an ultrasonic frequency that emulsifies cataract tissue. The extracted tissue is then aspirated away through the hollow tip. Irrigation of the eye with a saline solution compensates for the loss of volume in the eye when the cataract tissue is removed.
Intended use:	Reprocessed Phacoemulsification Tips are intended to emulsify and excise cataract tissues in ophthalmic microsurgical procedures.
Indications statement:	Reprocessed Phacoemulsification Tips are indicated for use to emulsify and excise cataract tissues in patients requiring eye surgery.
Technological characteristics:	The design, materials, and intended use of the Reprocessed Phacoemulsification Tips are identical to the predicate devices. The mechanism of action of the Reprocessed Phacoemulsification Tip is identical to the predicate devices in that the same standard mechanical design, materials and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. Alliance Medical Corporation's reprocessing of Phacoemulsification Tips includes removal of adherent visible soil and decontamination. Each individual Phacoemulsification Tip is tested for appropriate function of its components prior to packaging, labeling, and sterilization operations.
Performance data:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Phacoemulsification Tip. • Biocompatibility • Validation of reprocessing • Optical comparator, irrigation function tests Performance testing demonstrates that Reprocessed Phacoemulsification Tips perform as originally intended.
Conclusion:	In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (the Reprocessed Phacoemulsification Tip) is safe, effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Alliance Medical Corporation
c/o Mr. Don Selvey
Vice President
Regulatory Affairs and Quality Assurance
10232 South 51st. Street
Phoenix, Arizona 85044

Re: K012637
Trade/Device Name: Reprocessed Phacoemulsification Tips
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: August 8, 2001
Received: August 13, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

NOV 0 7 2001

K012637

II. Indications for Use Statement

510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Phacoemulsification Tips

Indications for Use: Reprocessed Phacoemulsification Tips are indicated for use to emulsify and excise cataract tissues in patients requiring eye surgery.

Manufacturer	Description	Model
Alcon®	Phaco Tip Turbosonic	30KTS
Alcon®	Phaco Tip Turbosonic	30RT
Alcon®	Phaco Tip Microtip Round	30RTS
Alcon®	Phaco Tip Microtip Kelman	45KTS
Alcon®	Phaco Tip Turbosonic	45RT
Alcon®	Phaco Tip Microtip Round	45RTS
Alcon®	Phaco Tip Turbosonic	8065-7407-92
Alcon®	Phaco Tip Turbosonic	8065-7407-94
Alcon®	Phaco Tip Flared ABS	8065-740806
Alcon®	Phaco Tip Flared ABS	8065-740807
Alcon®	Phaco Tip Flared ABS	8065-740808
Alcon®	Phaco Tip Flared ABS	8065-740809
Alcon®	Phaco Tip Turbosonic ABS	8065-7900-20
Alcon®	Phaco Tip Turbosonic	8065-790021
Alcon®	Phaco Tip Turbosonic	8065-790022
Alcon®	Phaco Tip Turbosonic	8065-790023

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K012637

Prescription Use X or Over-the-Counter Use ____
(per 21 CFR 801.109)